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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,458	08/30/2001	Dwight D. Weller	50450-8038.US00	9454
22918	7590	01/05/2005	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/943,458

**Applicant(s)**

WELLER ET AL.

**Examiner**

Young J. Kim

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15-17 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-17 and 19-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action responds the Amendment received on September 29, 2004.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1-11, 15-17, and 19-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on June 29, 2004, is withdrawn in view of the claim amendments and arguments made in the Amendment received on September 29, 2004.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-11, 16, 17, 19, 20, and 23-27 under 35 U.S.C. 102(b) as being anticipated by Cummins et al. (U.S. Patent No. 5,874, 213, issued February 23, 1999), made in the Office Action mailed on June 29, 2004, is maintained for the reasons of record.

Applicants' arguments received on September 29, 2004 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments are addressed in the same order received.

Applicants traverse the rejection stating that the claimed method is drawn to separating a population of duplexes, each comprising one of a population of different oligomeric analyte

Art Unit: 1637

molecules, which are substantially uncharged, hybridized with a specific probe molecule, which is fully charged (page 7, section IV).

This is not found persuasive because the method clearly recites the phrase, “said specific probe molecule is a *nucleic acid* or fully charged nucleic acid analog, and the fully charged probe molecule is defined in the instant specification as being DNA or RNA (page 12, lines 21-22).

MPEP 2106(II)(C) states that while it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not impose that limitation.

Cummins et al. clearly discloses a method involving the hybridization of PNA to target nucleic acids, wherein said target nucleic acid is DNA or RNA (column 3, lines 48-50). In Applicants’ own words, nucleic acids are “highly charged oligomers.” (page 5, Response). While Cummins et al. terms this as target nucleic acids while Applicants terms it as “probe” is irrelevant, for the characteristics of both are the same.

With regard to analyte molecules being composed of linked subunits of which are at least 90% uncharged, Cummins et al. employ Peptide Nucleic Acids, the same analyte molecules Applicants employ in their own method:

“As stated above, a ‘substantially uncharged’ oligomeric molecule, in context of the invention, is an oligonucleotide analog in which all of the nucleotide subunits are uncharged ... [e]xamples of well known uncharged oligonucleotide analogs include peptide nucleic acid...” (emphasis added, page 11, lines 23-29, Specification).

Art Unit: 1637

Therefore, the method of Cummins et al. forms a duplex with a highly charged oligomeric compound (DNA or RNA) with uncharged oligomeric compound (PNA). Clearly, such method step is anticipated by the artisans.

With regard to Applicants' argument regarding the claimed invention as being "opposite" of the method disclosed by Cummins et al., the argument is not found persuasive for the following reasons.

According to the instant specification, the "duplex" involved in the instant application involves two oligomeric compounds – DNA/RNA (page 12, lines 21-22); and neutrally charged (or uncharged) oligomeric compound (i.e., PNA) (page 11, lines 28-30).

The instant specification terms DNA/RNA as the "probe" and the uncharged oligomeric compound as the "analyte." While the terms appear to be "opposite" from the terms employed by Cummins et al., in fact they are not different.

Specifically, the instant specification discloses that the "probes" (or DNA/RNA), which is complementary to the "analyte" molecules, are derived from samples (i.e., naturally occurring). The "target analyte" as termed by Cummins et al., is also derived from samples (i.e., naturally occurring).

While the specification discloses that "analytes" are uncharged oligomeric compounds, such uncharged oligomeric compounds are not found in nature, and thus need to be synthesized, just as the "probes" employed by Cummins et al.

In sum, both methods involve the production of duplex, wherein said duplex is formed between a naturally occurring charged nucleic acid and an uncharged (synthesized) oligomer

Art Unit: 1637

(i.e., PNA), and therefore, for the above reasons, Cummins et al. anticipate the invention as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claim 15 as being unpatentable over Cummins et al., . (U.S. Patent No. 5,874,213, issued February 23, 1999) in view of Ness et al. (U.S. Patent No. 6,613,508 B1, issued September 2, 2003, filed July 22, 1997), made in the Office Action mailed on June 29, 2004 is maintained for the reasons of record.

Applicants' arguments received on September 29, 2004 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments are addressed in the same order received.

With regard to Applicants' reiterated arguments pertaining to the deficiencies of Cummins et al., the arguments have been already addressed above.

With regard to the deficiencies of Cummins et al. in providing the motivation or the expectation of success for the combination, Applicants' arguments are not found persuasive.

As clearly recited in the previous Office Action, Ness et al. disclose a wide-range of well-known size separation methods among which is ion-exchange HPLC method (column 4, lines 10-25).

Art Unit: 1637

Cummins et al. disclose method of separating a duplex formed between nucleic acid and PNA. While the separation of the duplexes was performed by capillary electrophoresis, as evidenced by Ness et al., one of ordinary skill in the art would have readily recognized that any of the well-known size separation techniques would have been readily implemented with a reasonable expectation of success. *Such is even acknowledged by the Applicants*, wherein the instant specification discloses, “[a]ny charge-based separation technique useful for separating charged biopolymers may be used to separate the charged:uncharged duplexes formed by mixing the substantially uncharged analyte molecules with the charged nucleic acid or analog,” (page 13, lines 22-25, Specification).

Since Ness et al. clearly disclose that separation of duplexes can be achieved via many well-known separation techniques, ranging from capillary electrophoresis to ion-exchange HPLC (column 4, lines 10-25; column 40, lines 64-65), one of ordinary skill in the art, at the time the invention was made would have had a clear reasonable expectation of success in substituting the separation method of Cummins et al. with that of Ness et al. to arrive at the invention as claimed.

Additionally, the MPEP, at 2143.02, states that the prior art can be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success.

If Applicants are arguing that an explicit motivation be found in the primary reference (i.e., Cummins et al.) to combine the specific teachings of the cited reference (i.e., Ness et al.), Examiner would like to recite a paragraph from *in re Oetiker*, 977, F.2d 1443, 1448 (Fed. Cir. 1992).

“[T]here must be some teaching, reason, suggestion, or motivation found “in the prior art” or “in the prior art references” to make a combination to render an invention obvious within the meaning of 35 U.S.C. 103 (1998). Similar language appear in a number of opinions and if taken literally would mean that an invention cannot be held to have been obvious unless something specific in a prior art reference would lead an inventor to combine the teachings therein with

Art Unit: 1637

another piece of prior art. This restrictive understanding of the concept of obviousness is clearly wrong.... While there must be some teaching, reason, suggestion, or motivation to combine existing elements to produce the claimed device, it is not necessary that the cited references or prior art specifically suggest making the combination.... In sum, it is off the mark for litigants to argue, as many do, that an invention cannot be held to have been obvious unless a suggestion to combine the prior art teachings is found in a specific reference."

Although the cited artisans do not specifically point out a motivation to in their disclosure, an ordinarily skilled artisan would have been able to identify the need for the combination of the teachings without the disclosure of the instant application.

It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

The rejection of claims 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over Cummins et al. (U.S. Patent No. 5,874,213, issued February 23, 1999) in view of Valdivia et al. (WO 96/36734, November 21, 1996), made in the Office Action mailed on June 29, 2004, is maintained for the reasons of record.

Applicants' arguments received on September 29, 2004 have been fully considered but they are not found persuasive for the following reasons.



Applicants do not specifically argue why it would not be obvious to combine the teachings of Valdivia et al. with Cummins et al. in their argument, other than arguing the deficiencies of the Cummins et al. reference, which has already been addressed above. Therefore, the rejection is maintained for the reasons of record.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

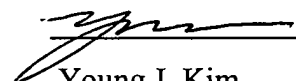
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge


Art Unit: 1637

of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
Young J. Kim  
Patent Examiner  
Art Unit 1637  
12/28/04

**YOUNG J. KIM**  
**PATENT EXAMINER**

yjk

  
**KENNETH R. HORLICK, PH.D**  
**PRIMARY EXAMINER**  
12/29/04